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EXAMINER	
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ART UNIT	PAPER NUMBER
1624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,202	MILLER ET AL.	
	Examiner	Art Unit	
	/Venkataraman Balasubramanian/	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21 and 23-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19,21 and 23-31* is/are rejected.

7)☒ Claim(s) *20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/6/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the Group I, claims 1-21 and 23-31 drawn to a compound of formula I and formula II, wherein Ring 1 is furan , Ring 2 is pyrimidinyl and A-B-C is Si-CH2-Si , composition and method of use in the reply filed on 1/25/2009 is acknowledged. Claims 1-21 and 23-31 will be examined to the extent they embrace the elected subject matter.

The traversal is on the ground(s) that the compound claims recited do not recite specific utility , that the compounds are useful for various therapies does not support the restriction requirement and that there is no serious search burden to search the entire application. This is not found persuasive for reasons of record. As for the applicants' traversal following apply.

As noted in the previous office action, the requirement for unity of invention is two-fold: (1) common utility and (2) sharing a substantial structural feature disclosed as being essential to the utility. Both these conditions are to be met with. Instant claims do not meet both these conditions.

As for applicants' traversal that there is no search burden, applicants should note that the present application is US application and in fact, search is not an issue in 371 application entering the national stage. The two criteria set forth in the previous restriction requirement, namely a substantially common structure essential for utility and the common utility, are factors to be considered in such cases. The compounds of Group I and Group II do not have the substantially common structural feature essential

for the utility and compounds of Group III are intermediates and do not share the same use as the final product. Thus, as noted before, both these criteria are not met with.

Examiner also noted in the previous office action "Should applicant traverse on the ground that the core species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention". Applicants have not asserted that the two groups are not distinct. Applicants have not submitted evidence or identified such evidence now of record showing the core group to be obvious variants or clearly admitted on the record that all core groups embraced in the instant inventions are equivalent. In which case, examiner needed not search all cores. A prior art , which anticipates any one of the groups embraced by a specific core, may then render rest of the core groups as obvious variant. In other words, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

References cited in the Information Disclosure Statement, filed on 3/6/2006, are made of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19, 21 and 23-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Recitation of " one of A, B, C comprises…" and "the compound does not comprise…" in the proviso at the end of claims 1, 23, 25 and 31 renders these claims and their dependent claims indefinite as the term "comprises" more than what is positively recited therein. See MPEP 2111.03 which states under transitional phrases The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., Genentech, Inc. v. Chiron Corp., 112 F.3d 495,501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

2. Claim 21 is an improper dependent claim as it fails to further limit claim 1 on which it is dependent. Claim 21 recites "which is in the form of single enantiomer or diastereoisomer or tautomer" and such limitations are not in claim 1.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating prostate hypertrophy does not reasonably provide enablement for treatment and or prevention of various diseases generically embraced in these claim language. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In evaluating the enablement question, several factors are to be considered. Note In re Wands, 8 USPQ2d 1400 and Ex parte Forman, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) level of skill in the art, 8) the quantity of experimentation needed.

1) The nature of the invention:

The instant method of use claims 25-31 are drawn to a method for treatment or prevention of endometriosis, uterine myoma, an ovarian disease, a mammary cystic disease, prostatic hypertrophy, amenorrhea, precocious puberty, premenstrual syndrome, a sex-steroid-dependent pathophysiology or benign prostatic hyperplasia, or to arrest spermatogenesis, a method for treatment or prevention of endometriosis with pain, polycystic ovarian disease or secondary amenorrhea, a method for treatment or prevention of Alzheimer's disease, a method for treatment or prevention of HIV infection

or AIDS, a method for treatment or prevention of a disease caused by thymic malfunction, a method for treatment or prevention of multiple sclerosis, rheumatoid arthritis or type 1 diabetes and a method for the treatment or prevention of cancer in general.

Instant claims, as recited, are reach through claims. A reach through claim is a claim drawn to a mechanistic, receptor binding or enzymatic functionality in general format and thereby reach through a scope of invention for which they lack adequate written description and enabling disclosure in the specification.

In the instant case, it appears that, because the instant compounds ability to antagonize gonadotropin releasing hormone, it is implicitly recited that, based on the mode of action, any or all conditions can be treated and prevented with the instant compounds for which there is no adequate written description and enabling disclosure. The scope of the claims includes not only any or all conditions but also those condition yet to be discovered for which there is no enabling disclosure. In addition, the scope of these claims includes treatment and prevention of various diseases, which is not adequately enabled solely based on the gonadotropin-releasing hormone receptor antagonist activity of the compounds provided in the specification at pages 1-3. In fact specification has no assays for gonadotropin-releasing hormone receptor antagonist activity. The instant compounds are disclosed to have gonadotropin-releasing hormone receptor antagonist activity and it is recited that the instant compounds are therefore useful in treating any or all sex-hormone related disorders, all cancers, all diseases due to thymic malfunction, including endometriosis, uterine myoma, an ovarian disease, a

mammary cystic disease, prostatic hypertrophy, amenorrhea, precocious puberty, premenstrual syndrome, a sex-steroid-dependent pathophysiology or benign prostatic hyperplasia, or to arrest spermatogenesis, endometriosis with pain, polycystic ovarian, diseases caused by thymic malfunction, multiple sclerosis, rheumatoid arthritis or type 1 diabetes and all cancer in general for which applicants provide no competent evidence. Moreover, the applicants have not provided any competent evidence that the instantly disclosed tests are highly predictive for all the uses disclosed and embraced by the claim language for the intended host.

The scope of the claims involves all of the millions of compounds of claim 1 as well as the thousand of diseases.

Proliferative disease would include benign tumors, malignant tumors, polyps, lumps, lesions, other pre-cancerous conditions, psoriasis, leukemia, the hyper proliferation of the gastric epithelium caused by the Helicobacter pylori infection of ulcers.

Cancer is just an umbrella term. Tumors vary from those so benign that they are never treated to those so virulent that all present therapy is useless. Accordingly, treatments for cancer are normally tailored to the particular type of cancer present, as there is no, and there can be no “magic bullet” against cancer generally.

Thus, the scope of claims is extremely broad.

More specifically, in the instant case, based on the mode of action of instant compounds as antagonist of gonadotropin-releasing hormone receptor activity without any assay or biological data disclosed in the specification, it is claimed that treating and

preventing any or all diseases and disorders including any or all cancers in general, for which there is no enabling disclosure. The scope of the claims includes any or all cancer based on the mode of action of the compound of instant claims for which there are no enabling disclosure. In addition, the scope of these claims as recited would include treatment of various cancers such as lung cancer, bone cancer, pancreatic cancer, skin cancer. cancer of the head or neck, cutaneous or intraocular melanoma, uterine cancer, ovarian cancer, rectal cancer, cancer of the anal region. stomach cancer, colon cancer, breast cancer, uterine cancer, carcinoma of the fallopian tubes, carcinoma of the endometrium, carcinoma of the cervix, carcinoma of the vagina, carcinoma of the vulva, Hodgkin's disease, cancer of the esophagus, cancer of the small intestine, cancer of the endocrine system, cancer of the thyroid gland, cancer of the parathyroid gland, cancer of the adrenal gland, sarcoma of soft tissue, cancer of the urethra, cancer of the penis, prostate cancer, chronic or acute leukemia, lymphocytic lymphomas, cancer of the bladder, cancer of the kidney or ureter, renal cell carcinoma, carcinoma of the renal pelvis, neoplasms of the central nervous system (CNS), primary CNS lymphoma, spinal axis tumors, brain stem glioma, pituitary adenoma, or a combination of one or more of the foregoing cancers, which is not adequately enabled solely based on the activity of the compounds provided in the specification.

The same applies for sex-steroid dependent pathophysiology, thymic malfunctions and other diseases specifically recited in the claims.

Moreover many if not most of diseases such as multiple sclerosis, Alzheimer's disease, HIV, AIDS, lung cancer, brain cancer, pancreatic cancer, colon cancer etc. are very difficult to treat and despite the fact that there are many anticancer drugs.

The scope of the invention includes millions of compounds of claim 1 as well as the thousand and thousand of diseases embraced in the claims.

No compound has ever been found to treat diseases of all types generally including cancers and sex related diseases, HIV or AIDS. Since this assertion is contrary to what is known in medicine, proof must be provided that this revolutionary assertion has merits. The existence of such a "compound" is contrary to our present understanding of oncology. Cecil Textbook of Medicine states, "each specific type has unique biologic and clinical features that must be appreciated for proper diagnosis, treatment and study" (see the enclosed article, page 1004). Different types of cancers affect different organs and have different methods of growth and harm to the body.

Also see the PTO website

<<http ://www.uspto.gov/web/offices/pac/dapp/1pecba.htm#7>>

ENABLEMENT DECISION TREE, Example F, situation 1) which is directed to the scope of cancer.

Also, note MPEP 2164.08(b) which states that claims that read on "... significant numbers of inoperative embodiments would render claims nonenabled when the specification does not clearly identify the operative embodiments and undue experimentation is involved in determining those that are operative.". Clearly that is the case here.

Thus, it is beyond the skill of oncologists today to get an agent to be effective against cancers generally. Note substantiation of utility and its scope is required when utility is "speculative", "sufficiently unusual" or not provided. See Ex parte Jovanovics, 211 USPQ 907, 909; In re Langer 183 USPQ 288. Also note Hoffman v. Klaus 9 USPQ 2d 1657 and Ex parte Powers 220 USPQ 925 regarding type of testing needed to support in vivo uses.

The scope of the claims includes not only treatment but also prevention of a various disease which is not adequately enabled solely based on the activity of the compounds as inhibitors provided in the specification at pages 1-3. "To prevent" actually means to anticipate or counter in advance, to keep from happening etc. (as per Websters II Dictionary) and there is no disclosure as to how one skilled in the art can reasonably establish the basis and the type of subject to which the instant compounds can be administered in order to have the "prevention" effect. There is no evidence of record, which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the disease(s) or disorder(s) claimed herein. However, the applicants have not provided any competent evidence that the instantly disclosed tests are highly predictive for all the uses disclosed and embraced by the claim language for the intended mammal. Moreover many if not most of diseases such as multiple sclerosis, Alzheimer's disease, various cancers and AIDS are very difficult to treat and hardly possible to prevent as claimed herein. In fact patient who underwent transplant have to be constantly treated with immunosuppressive medications. The fact that there are number of such drugs available and that they have

not been able to prevent contradicts instant invention. Note substantiation of utility and its scope is required when utility is "speculative", "sufficiently unusual" or not provided. See Ex parte Jovanovics, 211 USPQ 907, 909; In re Langer 183 USPQ 288 . Also note Hoffman v. Klaus 9 USPQ 2d 1657 and Ex parte Powers 220 USPQ 925 regarding type of testing needed to support in vivo uses.

Next, applicant's attention is drawn to the Revised Utility and Written Description Guidelines, at 66 FR 1092-1099, 2001 wherein it is emphasized that 'a claimed invention must have a specific and substantial utility'. The disclosure in the instant case is not sufficient to enable the instantly claimed method treating solely based on the gonadotropin-releasing hormone receptor antagonist activity disclosed for the compounds. The state of the art is indicative of the requirement for undue experimentation. See Huime and Lambalk (Lancet 358(9295): 1793-1803, 2001), which suggest that current status at best exploratory and need further experimentation. Note method of use for treating prostate cancer is taught therein.

2) The state of the prior art: The state of the art is indicative of the requirement for undue experimentation. Huime and Lambalk (Lancet 358(9295): 1793-1803, 2001), which suggest that current status at best exploratory and need further experimentation. In addition, there may be various possible adverse effects when a compound of formula (I) is given to a patient to treat any of the aforementioned diseases. Much experimentation and in vivo testing must be carried out to make sure that the administration of the compounds of formula (I) results in enhanced therapeutic effects without harmful side effects.

Hence, in the absence of showing of correlation between all the diseases claimed as capable of treatment and prevention with gonadotropin-releasing hormone receptor antagonist activity of instant huge genus of compounds, one of skill in the art is unable to fully predict possible results from the administration of the compounds of formula (I) due to the unpredictability of the role of the instantly claimed compounds. For example, since it is known that the challenge of cancer treatment has been to target specific therapies to pathogenetically distinct tumor types, that cancer classification has been based primarily on morphological appearance of the tumor and that tumor with similar histopathological appearance can follow significantly different clinical courses and show different responses to therapy.

Applicant's disclosure does not enable one of ordinary skill in the art to use the claimed invention within the entire scope of the diseases listed above. There is no compound, let alone an entire class of compounds that can treat the various and divergent diseases listed above, as claimed. Cell proliferation by various mode of action is still exploratory and requires further experimentation.

Those of skill in the art recognize that in vitro assays and or cell-cultured based assays are generally useful to observe basic physiological and cellular phenomenon such as screening the effects of potential drugs. However, clinical correlations are generally lacking. The greatly increased complexity of the in vivo environment as compared to the very narrowly defined and controlled conditions of an in- vitro assay does not permit a single extrapolation of in vitro assays to human diagnostic efficacy with any reasonable degree of predictability. In vitro assays cannot easily assess cell-

cell interactions that may be important in a particular pathological state. Furthermore it is well known in the art that cultured cells, over a period time, lose phenotypic characteristics associated with their normal counterpart cell type. Freshney. (Culture of Animal Cells, A Manual of Basic Technique, Alan R. Liss, Inc., 1983, New York, p4) teach that it is recognized in the art that there are many differences between cultured cells and their counterparts in vivo. These differences stem from the dissociation of cells from a three-dimensional geometry and their propagation on a two-dimensional substrate. Specific cell interactions characteristic of histology of the tissue are lost. The culture environment lacks the input of the nervous and endocrine systems involved in homeostatic regulation in vivo. Without this control, cellular metabolism may be more constant in vitro but may not be truly representative of the tissue from which the cells were derived. This has often led to tissue culture being regarded in a rather skeptical light (p. 4, see Major Differences/n Vitro). Further, although drawn specifically to cancer cells, Dermer (Bio/Technology, 1994, 12:320) teaches that, "petri dish cancer" is a poor representation of malignancy, with characteristics profoundly different from the human disease Further, Dermer teaches that when a normal or malignant body cell adapts to immortal life in culture, it takes an evolutionary type step that enables the new line to thrive in its artificial environment. This step transforms a cell from one that is stable and differentiated to one that is not. Yet normal or malignant cells in vivo are not like that. The reference states that evidence of the contradictions between life on the bottom of a lab dish and in the body has been in the scientific literature for more than 30 years. Clearly it is well known in the art that cells in culture exhibit characteristics different from

those in vivo and cannot duplicate the complex conditions of the in vivo environment involved in host-tumor and cell-cell interactions.

Applicants claim the treatment of various cancers. The state of the prior art is that cancer therapy remains highly unpredictable. The various types of cancer have different causative agents, involve different cellular mechanisms, and consequently, differ in treatment protocol. It is known that the challenge of cancer treatment has been to target specific therapies to pathogenetically distinct tumor types, that cancer classification has been based primarily on morphological appearance of the tumor and that tumors with similar histopathological appearance can follow significantly different clinical courses and show different responses to therapy (Golub et al., page 531). Furthermore, it is known that chemotherapy is most effective against tumors with rapidly dividing cells and that cells of solid tumors divide relatively slowly and chemotherapy is often less effective against them.

3) The predictability or lack thereof in the art: Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use for treating any or all condition of the instant compounds. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved". See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

4) The amount of direction or guidance present:

A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the compounds which fall within the scope of a claim will posses the alleged activity. The only direction or guidance present in the specification is the listing of diseases applicant considers treatable. Receptor activity is generally unpredictable and a highly structure specific area, and the data provided is insufficient for one of ordinary skill in the art to extrapolate to the other compounds of the claims.

The disclosure does not provide how this in vitro data correlates to the treatment of the assorted diseases claimed. The instant specification is short of any examples or data in regards to the supposed treating and preventing of the aforementioned diseases. Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use of the instant compounds. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

5) the presence or absence of working examples: Specification has no working examples to show treating and preventing any or all diseases including all cancers and the state of the art is that the effects of gonadotropin-releasing hormone receptor antagonist activity are unpredictable.

6) The breadth of the claims: The instant claims embrace use of a huge genus of compounds and any or all diseases and cancers caused by and/or associated with an gonadotropin-releasing hormone receptor activity.

7)The level of skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad use of the compounds of the instant claims for the treatment of the various claimed diseases as a result necessitating one of skill to perform an exhaustive search for which disorders can be treated and prevented by what compounds of the instant claims in order to practice the claimed invention.

8) The quantity of experimentation: The quantity of experimentation needed is undue experimentation. It would be an undue burden to one skilled in the pharmaceutical arts since there is inadequate guidance given to the skilled artisan, regarding the pharmaceutical use, for the reasons stated above. One of skill in the art would need to determine what diseases out of the multitude claimed would be benefited (i.e. treated) by the administration of the compounds of formula (I) and would furthermore have to determine which of the claimed compounds would provide treatment and prevention of which disease.

Thus, factors such as “sufficient working examples”, “the level of skill in the art” and “predictability”, etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims. In view of the breadth of the claims, the chemical nature of the invention, the unpredictability of enzyme-inhibitor interactions in general, and the lack of working examples regarding the activity of the claimed compounds towards treating the variety of diseases of the instant claims, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which diseases can be treated and prevented by the compounds encompassed in the instant claims, with no assurance of success.

MPEP §2164.01(a) states, “A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was 'filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).” That conclusion

is clearly justified here and undue experimentation will be required to practice Applicants' invention.

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

/Venkataraman Balasubramanian/

Primary Examiner, Art Unit 1624